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Indian Standard

SPECIFICATION FOR FORCEPS, RUBBER DAM CLAMP AND COTTON ROLL CLAMP, DENTAL

(First Revision)

- 1. Scope This standard specifies material, dimensions and other requirements for dental rubber dam clamp forceps and cotton roll clamp forceps.
- 2. Material Stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS: 6603-1972 'Specification for stainless steel bars and flats'.
- 3. Shape and Dimensions As shown in Fig. 1.
- 3.1 Tolerances on various dimensions shall be as given below:
 - a) ± 0.05 mm on dimensions up to 2.0 mm,
 - b) ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm.
 - c) ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm.
 - d) ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm,
 - e) ±1.0 mm on dimensions above 50.0 mm and up to 100.0 mm, and
 - f) ± 2.0 mm on dimensions above 100.0 mm.
- 4. Heat Treatment The forceps shall be uniformly hardened and tempered to 400 to 480 HV and the spring to 370 to 410 HV, when tested in accordance with IS: 1501 (Part 1)-1984 'Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (second revision)'.

5. Workmanship

- 5.1 The instrument shall be balanced.
- 5.2 The spring shall provide smooth, uniform and jerk-free opening and closing of the instrument.
- **5.3** The joint shall be box type, conforming to the relevant requirements of **6** of IS: 3642-1978 'General requirements for surgical instruments (*first revision*)'.
- 5.4 There shall be no sharp edges.
- 5.5 The working ends shall be as shown in the figure, so as to enable a rubber dam clamp or cotton roll clamp to be quickly placed on any tooth.
- 5.6 The ring shall slide easily and smoothly along the handles, securing the beaks in any desired position.

6. Surface Condition

- **6.1** General All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by inspection using normal vision (corrected, if necessary).
- 6.2 Surface Finish The surface finish shall be one of, or a combination of, the following:
 - a) Mirror polished;
 - b) Reflection-reducing, for example, satin finish, matt black finish; and
 - c) An applied surface coating, for example, for insulation purposes.
 - Note The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electro-polishing, and in addition, satin finishing (glass beading or satin brushing). The finish should be unifrom and smooth and it should reduce glare.

Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be effected by an appropriate procedure, such as polishing, brushing, electropolishing, and mirror buffing.

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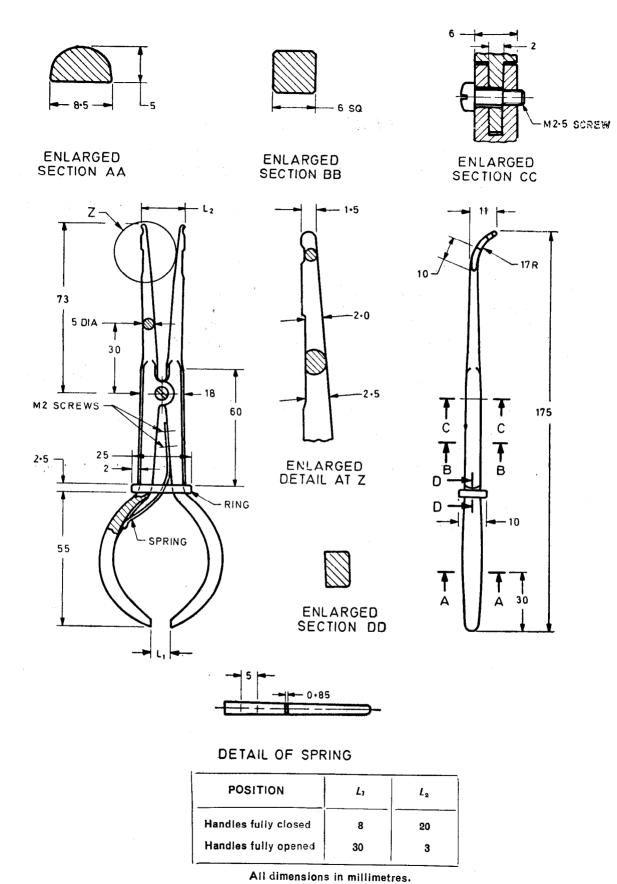


FIG. 1 FORCEPS, RUBBER DAM CLAMP AND COTTON ROLL CLAMP, DENTAL

6.3 Passivation and Final Treatment — The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 min at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

Note — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

7. Corrosion Resistance Test — The forceps shall be tested in accordance with IS: 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. The forceps shall show no sign of corrosion after the test.

8. Marking and Packing

- 8.1 The forceps shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel' or letters 'ss'; and the country of manufacture.
- 8.2 Each instrument shall be put in a polyethylene bag or wrapped in wax paper. The instruments shall then be packed in cartons in accordance with the current trade practice.
- 8.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.
- 8.3 The packages shall be marked with the name of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel'; and the country of manufacture.
- 8.4 Certification Marking Details available with the Bureau of Indian Standards.
- 9. Sampling Sampling procedure and acceptance criteria for the forceps shall be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given in Appendix A.

APPENDIX A

(Clause 9)

SAMPLING SCHEME AND CRITERIA FOR CONFORMITY FOR FORCEPS, RUBBER DAM CLAMP AND COTTON ROLL CLAMP, DENTAL

- A-1. Lot In any consignment, all the forceps produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.
- A-2. Scale of Sampling The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

(Clauses A-2, A-3.1 and A-3.2)

Lot Size	Sample Size	Sub-sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS: 4905-1968 'Methods for random sampling' may be followed.

A-3. Number of Tests and Criteria for Conformity

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship, and surface condition (visual). An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

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A-3.2 The lot having been found satisfactory according to A-3.1 shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to A-3.1. Each instrument in the sub-sample shall be subjected to hardness and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

EXPLANATORY NOTE

This standard was first issued in 1971. In this revision, tolerances on various dimensions have been specified, a recommended scheme of sampling has been added and the clauses on surface condition have been modified besides incorporating certain other modifications.